K011867

JUL 12 2001

Summary of Safety and Effectiveness
Liquid Assayed Multiqual® Control Levels 1, 2 and 3

1.0 Submitter

Bio-Rad Laboratories
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Date of Summary Preparation

June 8, 2001

2.0 Device Identification

Product Trade Name:	Liquid Assayed Multiqual® Control Levels 1, 2 and 3
Common Name:	Multi-Analyte Controls, (Assayed and unassayed)
Classifications:	Class I
Product Code:	75JJY
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

MULTIQUAL® ASY I, II, III
Ciba Corning Diagnostics Corp. (Bio-Rad Laboratories)
Irvine, California

Docket Number: K923633

4.0 Description of Device

Liquid Assayed Multiqual® Control is prepared from human serum to which purified biochemical material (tissue extracts of human and animal origin) chemicals, drugs, preservatives and stabilizers have been added.
The control is provided in liquid form for convenience.

5.0 Statement of Intended Use

Liquid Assayed Multiqual® Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in the package insert.

6.0 Comparison of the new device with the Predicate Device

The new Liquid Assayed Multiqual® Control claims substantial equivalence to the MULTIQUAL ASY I, II, III (K923633).

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio Rad Liquid Assayed Multiqual® Control Levels 1, 2 and 3 (New Device)	Bio Rad Liquid Assayed Multiqual® Control Levels 1, 2 and 3 (Predicate Device)
Similarities		
Intended Use	Liquid Assayed Multiqual® Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Use Multiqual® quality control material, assayed, to monitor the precision and the accuracy of general chemistry, immunochemistry, and therapeutic drug monitoring test procedures.
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based
Storage (Unopened Frozen)	–20°C or colder until expiration date	Below -10 °C until expiration date
Storage (Unopened Thawed)	2-8° C 30 days with the following exceptions: Total bilirubin values may decrease. Alkaline phosphatase activity may rise. The control must be stored frozen when using AST methods without pyridoxal-5-phosphate.	2-8° C 30 days with the following exceptions: Total bilirubin values may decrease. Alkaline phosphatase activity may rise. The control must be stored frozen when using AST methods without pyridoxal-5-phosphate.
Differences		
Open,Vial Claim	2-8° C for 14 days with the following exceptions: Total bilirubin will be stable for 10 days and LAP Arylamidase will be stable for 3 days.	2-8° C for 14 days with the following exceptions: Total bilirubin will be stable for 10 days.
Analytes	Same analytes as the predicate device with additional claims for the following: Acetaminophen, Alpha-1-Antitrypsin, Amikacin, Amylase (Pancreatic), Apolipoprotein A, Apolipoprotein B, C3 Complement, C4 Complement, Ceruloplasmin, Cholesterol-LDL, CK-MB Isoenzyme, Copper, Globulin,	Refer to the substantially equivalent product insert.

	Haptoglobin, Immunoglobulins (IgA, IgG, IgM), LAP-Arylamidase, Prealbumin, Prostatic Acid Phosphatase, Protein Electrophoresis and Transferrin.	

7.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquid Assayed Multiqual® Control. Product claims are as follows:

7.1 Open vial: Once the control material is thawed and opened, all analytes will be stable for 14 days when stored tightly capped at 2-8°C with the following exceptions: Total bilirubin will be stable for 10 days and LAP Arylamidase will be stable for 3 days. Avoid repeated freezing and thawing of the quality control material.

7.2 Closed vial: When the control material is thawed and stored unopened at 2-8°C, all analytes will be stable for 30 days with the following exceptions: Total bilirubin values may decrease; alkaline Phosphatase activity may rise. The control must be stored frozen when using AST methods without pyridoxal-5-phosphate.

7.3 Shelf life: Three years when stored at -20°C or colder. For optimum performance, avoid storage in a frost-free freezer. Store vials away from the light.

Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 12 2001

Ms. Donna Chapman
Quality Assurance/Regulatory Affairs Manager
Bio Rad Laboratories
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: 510(k) Number: K011867
Trade/Device Name: Liquid Assayed Multiqual® Control Levels 1, 2, and 3
Regulation Number: 862.1660
Regulatory Class: I, reserved
Product Code: JJY
Dated: June 8, 2001
Received: June 14, 2001

Dear Ms. Chapman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) Number (if known): K011867

Device Name: **Liquid Assayed Multiqual® Control Levels 1, 2 and 3**

Indications for Use:

An assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in the package insert.

Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 011867

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use_____